

#2 1632

RECEIVED

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
ATTORNEYS AT LAW
110 NEW YORK AVENUE, N.W., SUITE 600
WASHINGTON, D.C. 20005-3934

ROBERT GREENE STERNE
EDWARD J. KESSLER
JORGE A. GOLDSTEIN
SAMUEL L. FOX
DAVID K.S. CORNWELL
ROBERT W. EDMOND
TRACY-GENE G. DURKIN
MICHELE A. CIMBALA
MICHAEL B. RAY
ROBERT E. SOKOHL
ERIC K. STEFFE
MICHAEL O. LEE

STEVEN R. LUDWIG
JOHN M. COVERT*
LINDA E. ALCORN
RAZ E. FLESHNER
ROBERT C. MILLONG
MICHAEL V. MESSINGER
JUDITH U. KIM
TIMOTHY J. SHEA, JR.
DONALD R. MCPHAIL
PATRICK E. GARRETT
STEPHEN G. WHITESIDE
JEFFREY T. HELVEY*

HEIDI L. KRAUS
JEFFREY R. KURIN
RAYMOND MILLIEN
PATRICK D. O'BRIEN
LAWRENCE B. BUGAISKY
CRYSTAL D. SAYLES*
EDWARD W. YEE
ALBERT L. FERRO*
DONALD R. BANOWIT
PETER A. JACKMAN
MOLLY A. MCCALL
TERESA U. MEDLER

JEFFREY S. WEAVER
KRISTIN K. VIDOVICH
KENDRICK P. PATTERSON
DONALD J. FEATHERSTONE
GRANT E. REED
VINCENT L. CAPUANO
JOHN A. HARROUN*
MATTHEW M. CATLETT*
NATHAN K. KELLEY*
ALBERT J. FASULO II*
W. BRIAN EDGE*

PHONE: (202) 371-2600 FACSIMILE: (202) 371-2540
www.skgl.com

AUG 29 2000

TECH CENTER 1600/2900

KAREN R. MARKOWICZ**
SUZANNE E. ZISKA**
BRIAN J. DEL BUONO**
ANDREA J. KAMAGE**
NANCY J. LEITH**
TARJA H. NAUKKARINEN**

*BAR OTHER THAN D.C.
**REGISTERED PATENT AGENTS

WRITER'S DIRECT NUMBER:
(202) 371-2673

INTERNET ADDRESS:
JCOVERT@SKGF.COM

August 25, 2000

Assistant Commissioner for Patents
Washington, D.C. 20231



Re: U.S. Utility Patent Application
Appl. No. 09/580,463; Filed: May 26, 2000
For: Cytotectin Dimers and Methods of Use Thereof
Inventors: WHEELER, Carl J.
Our Ref: 1530.0220001/JMC/MJD

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement (*in duplicate*);
2. Form PTO-1449 (19 pages, citing 68 documents);
3. Sixty-eight (68) cited documents (AA1, AB1, AC1, AD1, AE1, AF1, AG1, AH1, AI1, AJ1, AK1, AL1, AR1, AS1, AT1, AA2, AR2, AS2, AT2, AR3, AS3, AT3, AR4, AS4, AT4, AR5, AS5, AT5, AR6, AS6, AT6, AR7, AS7, AT7, AR8, AS8, AT8, AR9, AS9, AT9, AR10, AS10, AT10, AR11, AS11, AT11, AR12, AS12, AT12, AR13, AS13, AT13, AR14, AS14, AT14, AR15, AS15, AT15, AR16, AS16, AT16, AR17, AS17, AT17, AR18, AS18, AT18, and AR19); and
4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Art Unit: 1632

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

RECEIVED

AUG 29 2001

TECH CENTER 1600/2900

Assistant Commissioner for Patents
August 25, 2000
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this letter is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



John M. Covert
Attorney for Applicants
Registration No. 36,688

JMC/MJD/rjv
Enclosures

P:\USERS\MDOWD\1530\0220001\ptolids.trn

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

WHEELER, Carl J.

Appl. No. 09/580,463

Filed: May 26, 2000

For: **Cytotectin Dimers and Methods of Use Thereof**



Art Unit: 1632

Examiner: *To Be Assigned*

Atty. Docket:
1530.0220001/EKS/JMC/MJD

Information Disclosure Statement

Commissioner for Patents
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

The Examiner's attention is directed to related, commonly assigned, co-pending U.S. Appl. No. 08/565,756, filed November 30, 1995, and U.S. Appl. No. 09/092,486, filed June 5, 1998. The identification of the above U.S. Patent Applications is not to be construed as a waiver of secrecy as to the application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available

to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

This Information Disclosure Statement is being filed within three months of the U.S. filing date or before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

~ 292001

TECH CENTER 1600/2800

WHEELER, Carl J.
Appl. No. 09/580,463

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this pleading is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.


John M. Covert
Attorney for Applicant
Registration No. 38,759

Date: Aug. 25, 2000
1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600

P:\USERS\MDOWD\1530\022000\pto\IDS.wpd

FORM PTO-1449
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1530.0220001

APPLICATION NO.
09/580,463

APPLICANT
WHEELER, Carl

FILING DATE
May 26, 2000

O I P E
AUG 25 2000
PT GROUP
1632

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA1	4,713,339	12/15/1987	Levinson et al.	435	240.2	01/19/1983
AB1	4,897,355	01/30/1990	Eppstein et al.	435	240.2	01/07/1985
AC1	4,965,196	10/23/1990	Levinson et al.	435	691	01/19/1983
AD1	5,264,618	11/23/1993	Felgner et al.	560	224	04/19/1990
AE1	5,334,761	08/02/1994	Gebeyehu et al.	564	197	08/28/1992
AF1	5,459,127	10/17/1995	Felgner et al.	514	7	09/16/1993
AG1	5,580,859	12/03/1996	Felgner et al.	514	44	03/18/1994
AH1	5,589,466	12/31/1996	Felgner et al.	514	44	01/06/1995
AI1	5,676,954	10/14/1997	Brigham	424	450	05/08/1995
AJ1	5,693,622	12/02/1997	Wolff et al.	514	44	06/07/1995
AK1	5,703,055	12/30/1997	Felgner et al.	514	44	01/26/1994

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
✓ AL1	WO 94/29469	12/22/1994	WIPO			Yes No
AM1						Yes No
AN1						Yes No
AO1						Yes No
AP1						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

✓ AR 1 Agadjanyan, M.G., et al., "An HIV type 2 DNA Vaccine Induces Cross-Reactive Immune Responses against HIV type 2 and SIV," AIDS Res. Hum. Retroviruses 13(18):1561-1572 (December 1997).

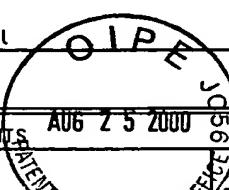
✓ AS 1 Agadjanyan, M.G., et al., "DNA Plasmid Based Vaccination Against the Oncogenic Human T Cell Leukemia Virus Type 1," Curr. Top. Microbiol. Immunol. 226:175-192 (1998).

✓ AT 1 Altman-Hamamdzic, S., et al., "Expression of β -galactosidase in mouse brain: utilization of a novel nonreplicative Sindbis virus vector as a neuronal gene delivery system," Gene Ther. 4(8):815-822 (August 1997).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>			ATTY. DOCKET NO. 1530.0220001		APPLICATION NO. 09/580,463		
			APPLICANT WHEELER, Carl				
			FILING DATE May 26, 2000				
			U. S. PATENT DOCUMENTS		GROUP 1632		
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	5,861,397	01/19/1999	Wheeler	514	247	10/03/1996
	AB2						
	AC2						
	AD2						
	AE2						
	AF2						
	AG2						
	AH2						
	AI2						
	AJ2						
	AK2						
FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2						Yes No
	AM2						Yes No
	AN2						Yes No
	AO2						Yes No
	AP2						Yes No
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
✓	AR	2	Bangham, et al., "Diffusion of Univalent Ions across the Lamellae," <i>J. Mol. Biol.</i> 23:238-252 (1965).				
✓	AS	2	Behr, J.P., et al.. "Efficient gene transfer into mammalian primary endocrine cells with Lipopolyamine-coated DNA," <i>Proc. Natl. Acad. Sci. U S A.</i> 86(18):6982-6986 (September 1989).				
✓	AT	2	Boyer, J.D., et al.. "In vivo protective anti-HIV immune responses in non-human primates through DNA immunization," <i>J. Med. Primatol.</i> 25(3):242-250 (June 1996).				
EXAMINER					DATE CONSIDERED		
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.							

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT				ATTY. DOCKET NO. 1530.0220001		APPLICATION NO. 09/580,463	
				APPLICANT WHEELER, Carl		FILING DATE May 26, 2000	
				P A T E P U. S. PATENT DOCUMENTS		O I P E P A T E N T & T R A D E M A R K O F F I C E AUG 25 2000 51 GROUP 1632	
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME			
AA3							
AB3							
AC3							
AD3							
AE3							
AF3							
AG3							
AH3							
AI3							
AJ3							
AK3							
FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY			
AL3							
AM3							
AN3							
AO3							
AP3							
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
✓	AR	3	Boyer, J.D., et al., "DNA Vaccination as Anti-Human Immunodeficiency Virus Immunotherapy in Infected Chimpanzees," J. Infect. Dis. 176(6):1501-1509 (December 1997).				
✓	AS	3	Boyer, J.D., et al., "Protection of chimpanzees from high-dose heterologous HIV-1 challenge by DNA vaccination," Nature Med. 3(5):526-532 (May 1997).				
✓	AT	3	Davis, H.L., "Plasmid DNA expression systems for the purpose of immunization," Curr. Opin. Biotechnol. 8(5):635-646 (October 1997).				
DATE CONSIDERED							
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.							

FORM PTO-1449
 INFORMATION DISCLOSURE STATEMENT
ATTY. DOCKET NO.
1530.0220001APPLICATION NO.
09/580,463APPLICANT
WHEELER, CarlFILING DATE
May 26, 2000

U.S. PATENT DOCUMENTS

NAME

AUG 25 2000

PATENT & TRADEMARK OFFICE

U.S. GOVERNMENT

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

O I P E

Davis, H.L., et al., "DNA-based immunization against hepatitis B surface antigen (HBsAg) in normal and HBsAg-transgenic mice," Vaccine 15(8):849-852 (June 1997).

Davis, H.L., et al., "Direct gene transfer in skeletal muscle: plasmid DNA-based immunization against the hepatitis B virus surface antigen," Vaccine 12(16):1503-1509 (December 1994).

Davis, H.L., et al., "Immune-mediated destruction of transfected muscle fibers after direct gene transfer with antigen-expressing plasmid DNA," Gene Ther. 4(3):181-188 (March 1997).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT		ATTY. DOCKET NO. 1530.0220001	APPLICATION NO. 09/580,463
		APPLICANT WHEELER, Carl	FILING DATE AUG 25 2000 May 26, 1990
		GROUP 1632	

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA3							
AB3							
AC3							
AD3							
AE3							
AF3							
AG3							
AH3							
AI3							
AJ3							
AK3							

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3						Yes No
	AM3						Yes No
	AN3						Yes No
	AO3						Yes No
	AP3						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

✓	AR	5	DeBruyne, L.A., et al., "Lipid-mediated gene transfer of viral IL-10 prolongs vascularized cardiac allograft survival by inhibiting donor-specific cellular and humoral immune responses," <i>Gene Ther.</i> 5(8):1079-1087 (August 1998).
✓	AS	5	Duzgunes, N., "Membrane fusion," in <i>Subcellular Biochemistry</i> . Rodyn, D.B., ed., Plenum Press, New York, Vol. 11, pp.195-286 (1985).
✓	AT	5	Etchart, N., et al., "Class I-restricted CTL induction by mucosal immunization with naked DNA encoding measles virus haemagglutinin," <i>J. Gen. Virol.</i> 78 (Pt 7):1577-1580 (July 1997).

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 1530.0220001
APPLICANT WHEELER, Carl
FILING DATE May 26, 2000
APPLICATION NO. 09/580,463

O P E
AUG 25 2000
S C S
PATENT & TRADEMARK OFFICE

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA3						
AB3						
AC3						
AD3						
AE3						
AF3						
AG3						
AH3						
AI3						
AJ3						
AK3						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AL3						Yes
AM3						No
AN3						Yes
AO3						No
AP3						Yes

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

✓	AR	6	Felgner, P.L., et al., "Lipofection: A highly efficient, lipid-mediated DNA-transfection procedure," Proc. Natl. Acad. Sci. U.S.A. 84(21):7413-7417 (November 1987).
✓	AS	6	Felgner, J.H., "Separation and Quantitation of Cationic Liposome Components by High Performance Liquid Chromatography with Evaporative Light-Scattering Detection," Pharm Res. 14(9):1269-1271 (September 1997).
✓	AT	6	Felgner, P.L., "Nonviral Strategies for Gene Therapy," Sci. Am. 276:102-106 (June 1997).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 1530.0220001 APPLICATION NO. 09/580,463

APPLICANT
WHEELER, Carl

FILING DATE
May 26, 2000

O I P E
AUG 25 2000
L
S
C
S

GROUP
1632

U.S. PATENT DOCUMENTS

TRADEMARK OFFICE

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA3						
AB3						
AC3						
AD3						
AE3						
AF3						
AG3						
AH3						
AI3						
AJ3						
AK3						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AL3						Yes No
AM3						Yes No
AN3						Yes No
A03						Yes No
AP3						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

<input checked="" type="checkbox"/>	AR	7	Fukunaga, M., et al., "Liposome Entrapment Enhances the Hypocalcemic Action of Parenterally Administered C," <i>Endocrinology</i> 115(2):757-761 (August 1984).
<input checked="" type="checkbox"/>	AS	7	Gramzinski, R.M., et al., "Immune Response to a Hepatitis B DNA Vaccine in Aotus Monkeys: A Comparison of Vaccine Formulation, Route, and Method of Administration," <i>Mol Med</i> 4(2):109-118 (February 1998).
<input checked="" type="checkbox"/>	AT	7	Gregoriadis, G., et al., "Liposome-mediated DNA vaccination," <i>FEBS Lett.</i> 402(2-3):107-110 (February 1997).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT			ATTY. DOCKET NO. 1530.0220001	APPLICATION NO. 09/580,465		
			APPLICANT WHEELER, Carl	FILING DATE May 26, 2000		
						
			GROUP 1632			
			U.S. PATENT DOCUMENTS 			
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA3						
AB3						
AC3						
AD3						
AE3						
AF3						
AG3						
AH3						
AI3						
AJ3						
AK3						
FOREIGN PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AL3						Yes
AM3						No
AN3						Yes
AO3						No
AP3						Yes
						No
OTHER (including Author, Title, Date, Pertinent Pages, etc.)						
/	AR	8	Hartikka, J., et al., "An Improved Plasmid DNA Expression Vector for Direct Injection into Skeletal Muscle," Human Gene Ther. 7(10):1205-1217 (June 1996).			
/	AS	8	Heppel, J., et al., "Development of DNA vaccines for fish: vector design, intramuscular injection and antigen expression using viral haemorrhagic septicaemia virus genes as model," Fish and Shellfish Immunol. 8:271-286 (1998).			
/	AT	8	Horn, et al., "Cancer Gene Therapy Using Plasmid DNA: Purification of DNA for Human Clinical Trials," Human Gene Ther. 6:656-673 (1995).			
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.					DATE CONSIDERED	

FORM PTO-1449
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1530.0220001

APPLICATION NO.
09/580,463

APPLICANT

WHEELER, Carl

FILING DATE

May 26, 2000

O I P E
JCS

AUG 25 2000
02
GROUP
5632

U.S. PATENT DOCUMENTS

CLASS SUB-CLASS FILING DATE

EXAMINER
INITIAL

DOCUMENT NUMBER

DATE

NAME

AA3

AB3

AC3

AD3

AE3

AF3

AG3

AH3

AI3

AJ3

AK3

FOREIGN PATENT DOCUMENTS

CLASS SUB-CLASS TRANSLATION

EXAMINER
INITIAL

DOCUMENT NUMBER

DATE

COUNTRY

AI3

AM3

AN3

AO3

AP3

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

✓ AR 9 Ishii, N., et al., "Cationic Liposomes A Strong Adjuvant for a DNA Vaccine of Human Immunodeficiency Virus Type 1," AIDS Res. Hum. Retroviruses 13(16):1421-1428 (November 1997).

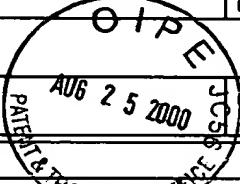
✓ AS 9 Kim, S., et al., "Preparation of Multivesicular Liposomes," Biochim. Biophys. Acta 728:339-348 (1983).

✓ AT 9 Klavinskis, L.S., et al., "Mucosal immunization with DNA-liposome complexes," Vaccine 15(8):818-820 (June 1997).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO. 1530.0220001	APPLICATION NO. 09/580,463
		APPLICANT WHEELER, Carl	FILING DATE May 26, 2000
			
U.S. PATENT DOCUMENTS			

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA3							
AB3							
AC3							
AD3							
AE3							
AF3							
AG3							
AH3							
AI3							
AJ3							
AK3							

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3						Yes No
	AM3						Yes No
	AN3						Yes No
	AO3						Yes No
	AP3						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

✓	AR	10	Klavinskis, L.S., et al., "Intranasal Immunization with Plasmid DNA-Lipid Complexes Elicits Mucosal Immunity in the Female Genital and Rectal Tracts," <i>J. Immunol.</i> 162(1):254-262 (January 1999).
✓	AS	10	Lodmell, D.L., et al., "Gene gun particle-mediated vaccination with plasmid DNA confers protective immunity against rabies virus infection," <i>Vaccine</i> 16(2-3):115-118 (January-February 1998).
✓	AT	10	Lodmell, D.L., et al., "DNA immunization protects nonhuman primates against rabies virus," <i>Nature Med.</i> 4(8):949-952 (August 1998).

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1530.0220001APPLICATION NO.
09/580,463APPLICANT
WHEELER, CarlFILING DATE
May 26, 2000O P E R A T I O N
AUG 25 2000
95
U. S. PATENT DOCUMENTS
PATENT & TRADEMARK OFFICEGROUP
1632

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA3						
AB3						
AC3						
AD3						
AE3						
AF3						
AG3						
AH3						
AI3						
AJ3						
AK3						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AL3						Yes
AM3						No
AN3						Yes
AO3						No
AP3						Yes

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

✓	AR	11	Mayer, L.D., et al., "Vesicles of variable sizes produced by a rapid extrusion procedure," Biochim. Biophys. Acta. 858(1):161-168 (June 1986).
✓	AS	11	Mayhew, E., et al., "Characterization of Liposomes Prepared Using a Microemulsifier," Biochim. Biophys. Acta. 775(2):169-174 (August 1984).
✓	AT	11	Nishizawa, et al., "Anion Recognition by Urea and Thiourea Groups: Remarkably Simple Neutral Receptors for Dihydrogenphosphate," Tetrahedron Lett. 36(36):6483-6486 (1995).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO. 1530.0220001	APPLICATION NO. 09/580,463
		APPLICANT WHEELER, Carl	O P E AUG 25 2000 P A T E N T & T R A D E M A R K O F F I C E
		FILING DATE May 26, 2000	

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3						
	AB3						
	AC3						
	AD3						
	AE3						
	AF3						
	AG3						
	AH3						
	A13						
	AJ3						
	AK3						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3						Yes No
	AM3						Yes No
	AN3						Yes No
	AO3						Yes No
	AP3						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

✓	AR	12	Okada, E., et al., "Intranasal Immunization of a DNA Vaccine with IL-12- and Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF)-Expressing Plasmids in Liposomes Induces Strong Mucosal and Cell-Mediated Immune Responses Against HIV-1 Antigens," <i>J. Immunol.</i> 159(7):3638-3647 (October 1997).
✓	AS	12	Olson, F., et al., "Preparation of Liposomes of Defined Size Distribution by Extrusion Through Polycarbonate Membranes," <i>Biochim. Biophys. Acta.</i> 557(1):9-23 (October 1979).
✓	AT	12	Qin, Y.J., et al., "Gene Suture--A Novel Method for Intramuscular Gene Transfer and its Application in Hypertension Therapy," <i>Life Sci.</i> 65(21):2193-2203 (1999).

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1530.0220001

APPLICATION NO.
09/580,463

APPLICANT
WHEELER, Carl
FILING DATE
May 26, 2000



U.S. PATENT DOCUMENTS

PATENT & TRADEMARK OFFICE

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA3						
AB3						
AC3						
AD3						
AE3						
AF3						
AG3						
AH3						
AJ3						
AK3						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AL3						Yes
AM3						No
AN3						Yes
AO3						No
AP3						Yes

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	13	Sambrook, et al., in Molecular Cloning. A Laboratory Manual, 2 nd ed., Cold Spring Harbor Laboratory Pres, p. A-2 (1989).
✓	AS	13	Sasaki, S., et al., "Monophosphoryl Lipid A Enhances Both Humoral and Cell-Mediated Immune Responses to DNA Vaccination Against Human Immunodeficiency Virus Type 1," Infect. Immun. 65(9):3520-3528 (September 1997).
/	AT	13	Sasaki, S., et al., "Adjuvant effect of Ubenimex on a DNA vaccine for HIV-1," Clin. Exp. Immunol. 111(1):30-35 (January 1998).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO. 1530.0220001	APPLICATION NO. 09/580,463
		APPLICANT WHEELER, Carl	O P E AUG 25 2000 C56 GROUP 1632
		FILING DATE May 26, 2000	

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3						
	AB3						
	AC3						
	AD3						
	AE3						
	AF3						
	AG3						
	AH3						
	AI3						
	AJ3						
	AK3						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3						Yes No
	AM3						Yes No
	AN3						Yes No
	AO3						Yes No
	AP3						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

✓	AR	<u>14</u>	Sasaki, S., et al., "Induction of Systemic and Mucosal Immune Responses to Human Immunodeficiency Virus Type 1 by a DNA Vaccine Formulated with QS-21 Saponin Adjuvant via Intramuscular and Intranasal Routes," <i>J. Virol.</i> 72(6):4931-9 (June 1998).
✓	AS	<u>14</u>	Schrijver, R.S., et al., "Immunization of cattle with a BHV1 vector vaccine or a DNA vaccine both coding for the G protein of BRSV," <i>Vaccine</i> 15(17-18):1908-1916 (December 1997).
✓	AT	<u>14</u>	Stephan, D.J., et al., "A New Cationic Liposome DNA Complex Enhances the Efficiency of Arterial Gene Transfer <i>In Vivo</i> ," <i>Human Gene Ther.</i> 7(15):1803-1812 (October 1996).

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1530.0220001

APPLICATION NO.
09/580,463

APPLICANT

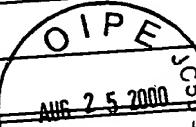
WHEELER, Carl

FILING DATE
May 26, 2000

GROUP
1632

AUG 25 2000

SC



U.S. PATENT DOCUMENTS

U.S. PATENT & TRADEMARK OFFICE

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA3						
AB3						
AC3						
AD3						
AE3						
AF3						
AG3						
AH3						
AI3						
AJ3						
AK3						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AL3						Yes No
AM3						Yes No
AN3						Yes No
AO3						Yes No
AP3						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

<input checked="" type="checkbox"/>	AR	15	Strauss, J.K., et al., "DNA bending by hexamethylene-tethered ammonium ions," Proc. Natl. Acad. Sci. U.S.A. 93(18):9515-9520 (September 1996).
<input checked="" type="checkbox"/>	AS	15	Szoka, F., et al., "Procedure for preparation of liposomes with large internal aqueous space and high capture by reverse-phase evaporation," Proc. Natl. Acad. Sci. U.S.A. 75(9):4194-4198 (September 1978).
<input checked="" type="checkbox"/>	AT	15	Ulmer, J.B., et al., "Heterologous Protection Against Influenza by Injection of DNA Encoding a Viral Protein," Science 259(5102):1745-9 (March 1993).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>			ATTY. DOCKET NO. 1530.0220001	APPLICATION NO. 09/580,463
			APPLICANT WHEELER, Carl	FILING DATE May 26, 2000
			O / P AUG 26 2000 PATENT & TRADEMARK OFFICE U.S. GOVERNMENT	GROUP 1632

U. S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA3							
AB3							
AC3							
AD3							
AE3							
AF3							
AG3							
AH3							
AI3							
AJ3							
AK3							

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3						Yes No
	AM3						Yes No
	AN3						Yes No
	AO3						Yes No
	AP3						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

X	AR	<u>16</u>	Ulmer, J.B., et al., "DNA Vaccines for Bacteria and Viruses," <i>Adv. Exp. Biol.</i> 397:49-53 (1996).
X	AS	<u>16</u>	Ulmer, J.B., et al., "DNA vaccines," <i>Curr. Opin. Immunol.</i> 8(4):531-536 (August 1996).
X	AT	<u>16</u>	Ulmer, J.B., et al., "Generation of MHC class I-restricted cytotoxic T lymphocytes by expression of a viral protein in muscle cells: antigen presentation by non-muscle cells," <i>Immunology</i> 89(1):59-67 (September 1996).

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT		ATTY. DOCKET NO. 1530.0220001	APPLICATION NO. 09/580,463
		APPLICANT WHEELER, Carl	AUG 25 2000 JCS
		FILING DATE May 26, 2000	

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA3							
AB3							
AC3							
AD3							
AE3							
AF3							
AG3							
AH3							
AI3							
AJ3							
AK3							

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3						Yes No
	AM3						Yes No
	AN3						Yes No
	A03						Yes No
	AP3						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

X	AR	17	Ulmer, J.B., et al., "Toward the development of DNA vaccines," <i>Curr. Opin. Biotechnol.</i> 7(6):653-658 (December 1996).
X	AS	17	Vahlsing, H.L., et al., "Immunization with plasmid DNA using a pneumatic gun," <i>J. Immunol. Methods</i> 175(1):11-22 (September 1994).
X	AT	17	Vanderzanden, L., et al., "DNA Vaccines Expressing either the GP or NP Genes of Ebola Virus Protect Mice from Lethal Challenge," <i>Virology</i> 246(1):134-44 (June 1998).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO. 1530.0220001	APPLICATION NO. <i>O I P E</i> 09/580,463
		APPLICANT WHEELER, Carl	FILING DATE May 26, 2000
		GROUP 1632	

AUG 25 2000

JC63

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3						
	AB3						
	AC3						
	AD3						
	AE3						
	AF3						
	AG3						
	AH3						
	AI3						
	AJ3						
	AK3						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3						Yes No
	AM3						Yes No
	AN3						Yes No
	AO3						Yes No
	AP3						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

X	AR	18	Wang, B., et al., "Mucosal immunization with a DNA vaccine induces immune responses against HIV-1 at a mucosal site," <i>Vaccine</i> 15(8):821-825 (June 1997).
X	AS	18	Wheeler, C.J., et al., "A novel cationic lipid greatly enhances plasmid DNA delivery and expression in mouse lung," <i>Proc. Natl. Acad. Sci. U S A.</i> 93(21):11454-11459 (October 1996).
X	AT	18	Wheeler, C.J., et al., "Converting an alcohol to an amine in a cationic lipid dramatically alters the co-lipid requirement, cellular transfection activity and the ultrastructure of DNA-cytosin complexes," <i>Biochim. Biophys. Acta</i> 1280(1):1-11 (April 1996).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1530.0220001

APPLICATION NO.
09/580,463

APPLICANT
WHEELER, Carl

FILING DATE
May 26, 2000

GROUP
1632



U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILED DATE
AA3						
AB3						
AC3						
AD3						
AE3						
AF3						
AG3						
AH3						
AI3						
AJ3						
AK3						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3					Yes No
	AM3					Yes No
	AN3					Yes No
	AO3					Yes No
	AP3					Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

<input checked="" type="checkbox"/>	AR	19	Yokoyama, M., et al., "DNA immunization: Effects of vehicle and route of administration on the induction of protective antiviral immunity," FEMS Immunol. Med. Microbiol. 14(4):221-230 (July 1996).
	AS	19	
	AT	19	

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.